

Fast Track Drug Development Programs: Designation and Review Programs
SOPP 8414
Appendix 7
Review for Determining Fast Track Development Program Designation

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Receipt Date of Fast Track Request _____ Date of Review Memo _____

IND number _____ Amendment number _____

Product _____

Sponsor _____

Condition for which the drug is intended and the specific anticipated benefits of use: (State clearly and concisely since the wording will be used in the designation letter)

A. Consideration of Fast Track Elements:

	Yes	No
1. Is the aspect(s) of the condition anticipated to be benefited serious or life-threatening? (See Section II/A) Fast Track Guidance	*	

	Yes	No
2. Does the drug show potential (given its stage of development) to treat this serious aspect of the condition? (See Section II/B) Fast Track Guidance		*

	Yes	No
3. Is the drug development program designed to determine whether the drug will affect a serious aspect of the condition? (Degree of specificity should be appropriate to the stage of development)		*

	Yes	No
4. Is there any accepted/approved treatment for the same serious or life-threatening aspect of the condition being studied?		*

	Yes	No
If yes, will the development program for the product assess the ability to address an unmet medical need in one or more of the following ways? (Check all that apply) (See Section II/A) Fast Track Guidance		*

_____ i. Improved effect(s) on serious outcome that represents an improvement over existing therapy?

_____ ii. Ability to provide benefit(s) in patients who are unable to tolerate or are unresponsive to alternative?

*Go To Section B.

_____ iii. Ability to provide benefit(s) similar to those of alternatives while avoiding serious toxicity?

_____ iv. Ability to provide benefit(s) similar to those of alternatives but with improvement in some factor such as compliance or convenience that will be shown to lead to favorable effect on serious outcome?

B. Recommendation: (If recommending designation, provide wording as to what aspect of the disease is being studied under fast track. If not recommending designation, provide a brief explanation of how specific criteria were not met. This wording should be able to be used in the letter to the sponsor.)

Fast Track Development Program is (check one)

granted_____

denied_____

Reviewer Signature/Date_____

Concurrence by Branch Chief:

Signature/Date_____

Concurrence by Division Director:

Signature/Date_____